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PHOENIX
TRANSLATIONS

August 14, 2009

Re: Japanese Kokai Patent Application No. H06[1994]-245989

To Whom It May Concern:

This is to certify that the above-referenced document (.pdf file "106-20530_JP6-245989A") has been translated from Japanese into English by a professional translator on our staff who is skilled in the Japanese language.

The attached English translation conforms essentially to the original Japanese except for those words or phrases for which there are no equivalents. Such words or phrases are noted in the translation along with the best English meaning.

Kim Kyle

Subscribed and sworn to before me on August 14, 2009.

Charles Wilkinson
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CHARLES WILKINSON
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My Commission Expires
January 05, 2011

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(54) SUTURE YARN FOR [USED IN] SURGERY AND MANUFACTURING METHOD THEREOF

(57) **Abstract**

Purpose

To provide a suture yarn for surgery that has good uniformity of material quality, and is easily manufactured. Moreover, it has excellent operability, high tensile strength in highly humid environment and less tissue reaction inside the body.

Composition

Center thread 4 is created by twisting composite yarn 3 that is formed by silk fiber 1 and synthetic fiber 2. Again composite yarn 3 formed by silk fiber 1 and synthetic fiber 2 is knitted in the braided shape around this center thread 4 to form braiding yarn 5. Afterwards, the whole fiber is refined and subjected to a hot stretching process.

[Scope of patent claims]

[Claim 1] A manufacturing method of suture yarn for surgery characterized in that after knitting a composite yarn comprising silk fibers and synthetic fibers in a braided shape, the entire [thread] is refined and subjected to hot stretching process.

[Claim 2] A manufacturing method of the suture yarn for surgery according to Claim 1, characterized in that the center thread is created by twisting the composite yarn comprising silk fibers and synthetic fibers, and after braiding yarn is formed with said composite yarn that was knitted around the center thread in a braided shape, the entire thread is refined and subjected to hot stretching process.

[Claim 3] Manufacturing method of the suture yarn for surgery according to Claim 1 and Claim 2, characterized in that the hot stretching process is carried out at 160°C-220°C at degree of elongation between 110%-120%.

[Claim 4] Suture yarn for surgery characterized in that a composite yarn comprising silk fibers and synthetic fibers is formed by knitting in a braided shape, and the entire thread is refined and subjected to a hot stretching process.

[Claim 5] Suture yarn for surgery described in Claim 4, characterized in that it comprises a center thread that is formed by twisting the composite yarn comprising silk fibers and synthetic fibers, and a braiding yarn of said composite yarn provided surrounding said center thread, and formed by knitting in a braided shape, and after that the entire thread is refined and subjected to hot stretching process.

DETAILED DESCRIPTION OF THE INVENTION

[0001]

Field of industrial application

This invention is related to the suture yarn for surgery and its manufacturing method.

[0002]

Prior art

Previously known suture yarn for surgery are roughly classified into suture yarn that uses silk as the raw materials and threads that use synthetic fiber as raw material. Among these, benefits of the suture yarn that uses silk as the raw material are: the feeling when sliding the thread at the time of operation is excellent, operability is excellent, and it can form firm nodes (knots). On the other hand, it also has demerits such as it can easily trigger off tissue reaction inside the body as a foreign substance, it has low tensile strength (in other words, it can break easily) and it lacks homogeneity. Particularly, the main disadvantage is that it [the thread] has low intensity at the time of performing a surgical knot in humid conditions, which is the state when this thread is used in a surgery.

[0003]

As compared to the above mentioned silk-made thread, the suture yarn made by using synthetic fibers such as polyester, nylon, etc., as the raw material has merits such as high tensile strength, and less tissue reaction inside the body. On the other hand, as compared to the silk-made thread, it has demerits such as poor operability, and unstable surgical knots.

[0004]

In recent years, a center thread formed by synthetic fibers is inserted around the cover thread that is formed by breading the silk thread as shown in the examined patent publication no. H04[1992]-2668 to overcome the disadvantages of both types [of suture yarns].

[0005]

Problems to be resolved by the invention

In the suture yarn for surgery shown in said patent, the thread is strengthened by inserting center thread formed by synthetic fiber. For this, it is necessary for the rupture elongation of the center thread and cover thread surrounding it to be practically identical. Otherwise when this suture yarn is stretched by tensile force, the thread having low rupture elongation (usually it is the silk-made cover thread) will first reach the limit of elongation (rupture elongation) and will break. After that, the load will be imposed on the thread having only high rupture elongation (usually it is the center thread made by synthetic fiber) and break. Eventually, the rupture strength of the entire suture string will become lower than the sum of rupture strengths of the center thread and silk thread.

[0006]

However, it is very difficult to equalize the rupture elongation of the center thread and the cover thread that have absolutely different physical characteristics from each other. Moreover, as the synthetic thread is used in the center, and the silk thread is used for the cover thread surrounding it, the entire suture yarn lacks uniformity of the material quality.

[0007]

Considering such circumstances, this invention aims at a suture yarn for surgery and its manufacturing method in which the yarn has good uniformity of material quality, and is easily manufactured. Moreover, it has excellent operability, high tensile strength in highly humid environment and less tissue reaction inside the body.

[0008]

Means of solving the problems

The inventors of this invention carried out the research on the above mentioned suture yarn and as a result, they discovered manufacturing a suture yarn for surgery by braiding the composite yarn (hereafter called as hybrid silk) by combining the silk fiber and synthetic fiber,

and attempted to manufacture a suture yarn by the method of sequentially carrying out the combination of threads, twining, refining and braiding, which is similar to the prior manufacturing method. In the usual soap boiling process to remove the sericin from the raw silk, the synthetic fibers remarkably shrink more than the silk fiber, and as a result it was clear that the braiding process is not possible as both the fibers are disentangled. However, with committed research these inventors succeeded in manufacturing a suture yarn for surgery that is superior than the thread manufactured by previous art using the above mentioned hybrid silk.

[0009]

This invention offers a manufacturing method for suture yarn for surgery in which silk thread and synthetic fiber are combined to form a composite yarn. This fiber is knitted in a braided shape and after that the entire thread is refined and subjected to hot stretching process. More preferable method to manufacture the suture yarn for surgery is the method in which silk thread and synthetic fiber are combined to form a composite yarn. This composite yarn is twisted to form a center thread. The composite yarn is knitted in a braided shape around this center thread to form a braided yarn. After this, the entire thread is refined and subjected to hot stretching process.

[0010]

Moreover, this invention provides the suture yarn for surgery that is manufactured by braiding the composite yarn formed by silk and synthetic fiber, and then refining and hot stretching the entire thread. More preferably, the suture yarn should be prepared by a method in which silk thread and synthetic fiber are combined to form a composite yarn. This composite yarn is twisted to form a center thread. The composite yarn is knitted in a braided shape around this center thread to form a braided yarn. After this the entire thread is refined and subjected to hot stretching process.

[0011]

Here, it is desirable if said hot stretching process is carried out [at a temperature] between 160°C-220°C, and at a stretching ratio between 110%-120%.

[0012]

Depending upon its manufacturing method and thread format, said composite yarn (hybrid silk) is roughly divided into a combined conjugate thread in which silk fibers and synthetic fibers are combined and adhered in the reeling process, a composite conjugated yarn in which silk fibers and synthetic fibers are combined and entangled in the reeling process, and a composite interlaced yarn in which the silk thread is randomly twined around the synthetic fiber. Other types of threads such as combined spun raw silk that is reeled by using synthetic fiber as the center thread and silk fiber as the discontinuous fiber, and various types of composite yarns formed by combining silk fiber and synthetic fiber can also be used.

[0013]

Operation of the invention

In the above mentioned method, at the time of braiding the two fibers, the silk fiber and synthetic fiber are not shrunk because refinement is not carried out until that time. Therefore, these two fibers can be braided excellently. After that, refinement is carried out. This process of carrying out hot stretching is more convenient than the process in which refinement is carried out before braiding as in the refinement process, and the synthetic fiber in the composite fiber shrinks more than the silk fiber. In said process, as braiding is carried out beforehand, this composite fiber is bound to each other. As a result, each braid of the string is strengthened and the surface of the thread also becomes smooth.

[0014]

As compared to the silk suture yarn of the past, the suture yarn for surgery manufactured by this method has high tensile strength. Particularly, the decreasing rate in the strength in humid environment is remarkably less as compared to the silk suture yarn. However, the same ductility and excellent operability similar to that of the silk suture yarn is maintained. Moreover, it has less tissue reaction inside the body as it contains the synthetic fiber. In addition, when the center thread and braided yarn both are formed from the composite yarn, the center thread is made of synthetic resin, and the braided thread is made of silk fiber. Uniformity of the material quality is higher than that of the composite yarn. And as for the rupture elongation, there is not much difference between silk fiber and braided yarn.

[0015]

Application Example

The Application Examples of this invention are explained with reference to Figure 1-Figure 4.

[0016]

First, in the first Application Example 1, as shown in Figure 2, it is a compound cohesive fiber 3 adhered with an oiling agent when the silk fiber 1 and synthetic fiber 2 are reeled while combining both [of silk thread 1 and synthetic fiber 2]. Hybrid silk fiber SN27-20 (the silk fiber of 27 deniers and the nylon of 0 denier) is used as a raw material and the suture yarn is manufactured as follows.

[0017]

(1) Doubling and twisted thread (process P1 in Figure 3): The above mentioned composite yarn 3 forms the 6 ply yarn doubling, and it is twisted at 478T/M with a synthetic fiber machine to form the Center thread 4 as shown in figure 1.

(2) Winding pipe (process P2): Braiding yarn 5 is winded (automatic pipe winder) automatically, it is winded around the pipe of braiding machine (Braider), and at the same time, the center thread 4 is winded around the bobbin for the center thread.

(3) Braiding (process P3): While putting above-mentioned center thread 4 in the Braider, the composite yarn 3 is knitted in a 16-ply braided shape and braiding yarn 5 is formed surroundings said center thread 4. At this time, each composite yarn 3 does not shrink as the refining process has not yet been carried out. Therefore, it can be easily braided without any disadvantages.

(4) Refinement (process P4): The entire suture yarn that consists of the above-mentioned center thread 4 and braiding yarn 5 is soaked in a Marseille soap solution, heated [at the temperature of] 85~90°C, and it is refined after around 1 hour. After washing by hot water for 25~30 minutes, air drying process is carried out.

(5) Dyeing (process P5): This is an optional procedure. For instance, the Hematine dye process is carried out when dyeing with black color.

(6) Coating (process P6): In this Application Example, as an ordinary method, beeswax and silicon are coated in this Application Example.

(7) Hot stretching processing (Setting heat: Process P7): Heat stretching machine is used. The processing speed, time, heating temperature, and draw ratio are properly adjusted to carry out the process. Concretely, the suture yarn has passed the furnace at about 2 m with a roller drawing machine, and the process is carried out for about 7 seconds at a fixed heating temperature and draw ratio. The heating temperature and the draw ratio will be described later.

[0018]

Suture yarn (SN2-0) of the corresponding USP 2-0 was manufactured by performing the above-mentioned process.

[0019]

Next, the Application Example 2 is explained. Here, 3-ply hybrid silk fiber SE40-20 (silk fiber of 40 deniers and polyesters of 20 deniers) are used as the raw material of above-mentioned center thread 4, the 12 ply of said SE40-20 are used as the raw material of braiding yarn 5. Additionally, the suture yarn (SE2-0) of corresponding USP2-0 was obtained by executing each process with conditions similar to that of Application Example 1.

[0020]

Next, the Application Example 3 is explained. In this Application Example, it is a composite interlaced yarn 3 that is entangled by air during the reeling process for the silk fiber 1 and synthetic fiber 2 as shown in Figure 3. The hybrid silk fiber SNC 14-10 (silk fiber of 14 deniers and nylons of 10 deniers) is used as the raw material. As shown in the Table 1, the suture yarn (SNC2-0) of corresponding USP2-0 was obtained by using the 12 ply in the center

thread, 36 ply in the braiding yarn, and by executing each process with the conditions similar to that of Application Examples 1 and 2.

[0021]

Various suture yarns were manufactured by changing the type and number of composition composite yarn 3 similarly to that in these Application Examples. The specific original thread composition is shown in the following Table 1. Moreover, an experimental result regarding various conditions are shown in Table 2 ~ Table 9.

[0022]

[Table 1]

Original thread composition of hybrid silk suture yarn

Type of original yarn	Specifications of suture yarn	(Braiding yarn)	Center thread	After refinement	
Composite conjugated yarn	SN 3－0	(SN14-10)x16	(SN27-10)x5	467.3 (479.3)	44.9
	2－0	(SN27-10)x16	(SN27-20)x6	708.4 (747.0)	39.5
Compound entangled thread	1－0	(SN27-20)x16	(SN27-10)x4x3	961.4 (1059.8)	45.8
	2	(SN40-10)x16	(SN27-20)x6x3	1874.0 (1984.5)	36.3
	SE 2－0	(SE40-20)x12	(SN40-20)x3	687.0 (747.0)	43.7
	1－0	(SE40-20)x12	(SN53-20)x6	883.4 (1059.8)	40.8
	2	(SE53-20)x16	(SN53-20)x6x3	1891.3 (1984.5)	36.0
	SNC 2－0	(SNC14-10)x2x16	(SNC14-10)x2x6	902.0 (747.0)	48.8

* (Total denier) = (Actual measurement of denier of the yarn) × 0.75 + (synthetic denier)

[0023]

Table 2

Hot stretching process of nylon fiber hybrid silk suture yarn

Sample	Temperature (°C)	Stretching ratio (%)	Straight Strength (kg)	Straight Elasticity (%)	Surgical knot Strength (kg)	Surgical knot Elasticity (%)
SN 2 - 0	160	120	3.371	13.5	2.273	11.2
	180	120	3.427	12.6	2.334	10.5
	200	120	3.564	18.3	2.375	12.4
SNC2-0 (Composite interlaced yarn)	180	120	3.697	13.6	2.556	8.97
	200	120	3.655	14.6	2.543	10.3
	220	120	3.669	14.2	2.563	10.4
	200	110	9.242	32.3	6.157	24.6
	220	110	9.200	29.9	6.016	23.6
	200	120	9.350	25.8	6.138	19.2
SN 2	220	120	9.388	22.9	5.984	17.6

*Processing speed : 20m/min Time: Approximately 7sec

Table 3

Processing of hot stretching of Nylon fiber hybrid silk suture yarn

Sample	Temperature (°C)	Stretching ratio (%)	Straight		Surgical knot	
			Strength (kg)	Elasticity (%)	Strength (kg)	Elasticity (%)
SE 2-0	180	110	3.194	20.6	2.058	10.6
	200	110	3.161	21.2	2.084	13.5
	180	120	3.341	12.6	1.957	8.8
	200	120	3.314	12.4	1.928	8.9
SE 2	200	110	8.805	28.1	5.959	20.1
	220	110	9.047	25.5	5.752	18.9
	200	120	9.108	22.7	5.865	14.5
	220	120	9.361	21.2	5.454	14.4

*Processing speed : 20m/min Time: Approximately 7sec

[0025]

Table 4

Physical properties of Nylon thread hybrid silk suture yarn (white)

Type of original yarn	Sample	Diameter (mm)	Straight			Straight		
			Strength (kg)	Tensile strength	Elasticity (%)	Strength (kg)	Tensile strength	Elasticity (%)
Compound conjugate thread	SN 3－0							
	Dry	0.238	2.203	49.5	14.8	1.534	34.5	11.0
	Wet	——	1.868	42.0	31.4	1.349	30.3	23.8
	SN 2－0							
	Dry	0.308	3.564	47.8	18.3	2.375	31.9	12.4
	Wet	——	2.992	40.2	36.8	2.004	26.9	28.1
	SN 1－0							
	Dry	0.377	4.514	40.4	16.5	3.164	28.4	13.8
	Wet	——	4.100	36.7	37.5	2.579	23.1	30.3
	SN 2							
	Dry	0.575	9.350	36.0	25.8	6.138	23.7	19.2
	Wet	——	8.033	31.0	43.4	4.806	18.5	39.7
Combined entangled thread	SNC 2－0							
	Dry	0.341	3.655	40.0	14.6	2.543	27.8	10.3
	Wet	——	3.282	35.9	34.8	2.107	23.1	26.3

* Each sample was subjected to hot stretched under the condition of 200°C and 120%.

[0026]

Table 5

Physical property of polyester hybrid silk suture yarns (White)

Type of original yarn	Sample	Diameter (mm)	Straight Strength (kg)	Straight Tensile strength (Kg/mm^2)	Straight Elasticity (%)	Surgical knot Strength (kg)	Surgical knot Tensile strength (Kg/mm^2)	Surgical knot Elasticity (%)
Composite conjugated yarn	SE 2-0							
	Dry	0.289	3.161	48.2	21.2	2.084	31.8	13.5
	Wet	——	2.816	42.9	33.8	1.797	27.4	21.3
	SE 1-0							
	Dry	0.338	4.221	47.1	18.9	2.601	29.0	11.3
	Wet	——	3.614	40.3	28.7	2.283	25.5	19.4
	SE 2							
	Dry	0.514	9.361	45.1	21.2	5.454	26.3	14.4
	Wet	——	7.723	37.2	34.0	4.504	21.7	26.0

*SE-1 is subjected to hot stretched under the condition of 200°C and 110%, and the other sample was subjected to hot stretched under the condition of 200°C and 120%.

[0027]

Table 6]

Comparative strengths of hybrid silk suture yarn and ordinary silk suture yarn

Sample standard	Total Denier of refinement (D)	Dry strength (Kg)		Wet strength (Kg)	
		Straight	Surgical knots	Straight	Surgical knots
SN 3-0	467.3	2.203	1.543	1.868	1.349
Silk 3-0	479.3	2.569	1.550	1.853	1.165
SN 2-0	708.4	3.564	2.375	2.992	2.004
SNC 2-0 (Composite interlaced yarn)	902.0	3.655	2.543	3.282	2.107
SE 2-0	687.0	3.161	2.084	2.816	1.797
Silk 2-0	747.0	3.841	2.244	2.819	1.740
SN 2	1874.0	9.350	6.138	8.033	4.806
SE 2	1891.3	9.361	5.464	7.723	4.504
Silk 2	1984.5	9.812	5.386	6.987	4.026

Calculated by

No. of deniers after refinement of silk (Deniers of the [illegible] yarn) x 0.75

[0028]

[Table 7]

Surgical strength of hybrid silk suture yarn at the time of humid climate

(Unit $kg/mm^{2)}$

Suture yarn Specifications	Silk	SN Hybrid silk (Composite conjugated yarn)	SE Hybrid silk (Composite conjugated yarn)	SNC Hybrid silk (Composite conjugated yarn)	Nylon Braiding	Polyethylene Braiding
3—0	23.0	30.3	——	——	31.5	43.0
2—0	21.4	26.9	27.4	23.1	26.7	38.1
1—0	18.2	23.1	25.5	——	27.0	31.8
2	15.3	18.5	21.7	——	25.5	26.7

[0029]
[Table 8]

Knot security of Nylon silk Hybrid silk suture yarn and tie down test.

Sample		Knot Security			Tie down		
		2surgical knots sliding resistance (kg)	3surgical knots	4surgical knots	Maximum value (kg)	Maximum value (kg)	Average value (kg)
SN 2-0	Dry	0.49	0/5	5/5	0.46	1.02	0.74
	Wet	0.60	0/5	5/5	0.55	0.75	0.65
SNC 2-0 (Composite interlaced yarn)	Dry	0.48	4/5	5/5	0.66	1.16	0.91
	Wet	0.75	0/5	5/5	0.66	0.85	0.76
Silk 2-0	DRY	0.31	3/5	5/5	0.53	0.92	0.73
	Wet	0.69	0/5	5/5	0.57	0.71	0.64
SN 1-0	Dry	0.57	4/5	5/5	0.78	1.40	1.09
	Wet	0.81	0/5	5/5	0.64	0.86	0.75
Silk 2-0	Dry	0.75	4/5	5/5	0.79	1.71	1.25
	Wet	0.78	0/5	5/5	0.76	0.98	0.87

*Knot security test result shows the number of cut ply after testing with 5 ply.
(Example 1/5 is 1 cut ply after testing 5 ply)

[0030]
[Table 9]

Knot security and tie down test of Polyester thread Hybrid silk suture yarn

Sample		Knot Security			Tie down		
		2 surgical knots sliding resistance (kg)	3 surgical knots	4 surgical knots	Maximum value (kg)	Maximum value (kg)	Average value (kg)
SNC 2-0 (Composite interlaced yarn)	Dry	0.26	1/5	5/5	0.65	1.03	0.64
	Wet	0.56	0/5	5/5	0.52	0.68	0.60
Silk 2-0	Dry	0.31	3/5	5/5	0.53	0.92	0.73
	Wet	0.69	0/5	5/5	0.57	0.71	0.64
SN 1-0	Dry	0.90	4/5	5/5	0.74	1.22	0.98
	Wet	0.68	0/5	5/5	0.67	0.84	0.76
Silk 2-0	Dry	0.75	4/5	5/5	0.79	1.71	1.25
	Wet	0.78	0/5	5/5	0.76	0.98	0.87

*Knot security test result shows the number of cut ply after testing 5 ply. (Example 1/5 is 1 cut ply after testing 5 ply)

[0031]

In the Table 2 and 3, an experimental result regarding heating temperature and draw ratio in the above mentioned hot stretching processing is shown. In both tables, the strength (tension load at the time of breaking) and rupture elongation of the state in which there is no surgical knot are shown in the "Straight" column. As shown in this table, though an almost satisfactory value is obtained within the range of 160□~220□ in heating temperature and 110%~120% in draw ratio, even among that ranges, around 200□ in heating temperature and around 120% in draw ratio are more preferable.

[0032]

Here, if the conventional silk suture yarn is processed at 200^0C and 120%, its strength is decreased considerably. Moreover, if the process is carried out for synthetic fiber suture yarn, though the set becomes inadequate easily, to improve the performance, heat treatment can be carried out without causing the inconvenience as stated above in the hybrid silk fiber of the present invention.

[0033]

In the Table 4 and 5, an experimental result regarding the tensile strength at the time of wet and dry process for the hybrid silk suture yarn was shown. As shown in the Table 4, the hybrid silk suture yarn of the nylon system meets the standard of the suture yarn in both the diameter and strength. As for the hybrid silk suture yarn of the polyester, the strength sufficiently meets the standard although the diameter is smaller (that is narrow) than the standard. Therefore, it can be expected that the suture yarn with high strength can be manufactured by increasing the raw material and increasing the diameter.

[0034]

As for the above-mentioned hybrid suture yarn and conventional silk suture yarn, an experimental result about comparison of strength difference at the time of Wet and Dry process was shown in Table 6. As shown in this table, the strength of the silk suture yarn at the time of wetting process is compared with the strength at the time of drying process: it is decreased by around 20-30%, and the decrease rate is limited to about 10-20% in the hybrid silk suture yarn. Moreover, though the comparative experimental result of the tensile strength (= strength/cross sectional area) at the time of wetting process was shown in the Table 7, as seen in this table, the surgical knot's strength at the time of wetting process of the hybrid silk suture yarn is improved by more than 20-40% as compared with the ordinary silk suture yarn. In general, since the suture yarn for surgery is usually used in the presence of body fluid and blood, etc., the surgical knot's strength at the time of wetting process as stated above can be an extremely preferable matter for the suture yarn.

[0035]

The result of knot security test related to the knot stability of said hybrid silk suture yarn and the result of the sliding-related tie down test were shown in the Table 8 and 9.

[0036]

These testing methods are carried out with the device shown in Figure 5 and 6. The knot security test is a method for obtaining the required number of knots without sliding the suture yarn at all to maintain the knot strength (tensile stress at the time of breaking). Square Knot (Square Knot) shown in Figure 5(b) of suture yarn 10 is tied twice, thrice, and this suture yarn 10 is pulled by the tensile tester as shown in the figure 5 (a). More concretely, both ends of suture yarn 10 are gripped with gripper 11 connected with distortion meter 16 and gripper 12 connected with cross head 14. The suture yarn 10 is pulled by making the cross head 14 fall as is, and the number of knots are obtained when the knot was broken. In addition, 18 is a recorder in Figure 5.

[0037]

In the tie down test, as shown in the figure 6, the suture yarn 10 is tied twice with the above mentioned square knot in a cylindrical shape sponge, and the both edges are fixed in both grippers 11 and 12 of the tensile tester. Next, the bottom edge is pulled at a constant speed by the cross head 14, and the resistance value is measured according to the knotted tie down.

[0038]

When both tests were carried out for the hybrid silk suture yarn and the silk suture yarn, equal results were obtained. As a result, it can be confirmed that the hybrid silk suture yarn had the knot stability and sliding equals with respect to the silk suture yarn. Moreover, it can be confirmed that the yarn has the smooth feeling of all silk suture yarns.

[0039]

In addition, in the present invention, regardless of types of the synthetic fiber, the types such as the above mentioned nylon, other polyesters and polypropylene are applicable.

[0040]

Moreover, although an explanation regarding the manufacturing of the suture yarn having a center thread was given in said Application Example, in this invention, the suture yarn for surgery utilizing the advantages of both silk thread and the synthetic fiber can also be obtained by knitting all the threads without the center thread similar to that of the above-mentioned.

[0041]

Effects of the Invention

As stated above, in the method of the present invention, all threads are refined after (most preferably, after forming the center thread by twisting the composite yarn comprising the silk thread and the synthetic fiber, and after forming the braiding yarn by knitting the composite yarn comprising the silk thread and the synthetic fiber surroundings this center thread in a braided shape) knitting the composite yarn comprising the silk thread and the synthetic fiber. As it is subjected to hot stretching process, the shrinking percentage of the suture yarn can be decreased by performing refining process, and the suture yarn made of hybrid silk can be manufactured by performing the hot stretching process along with the braiding process easily under the condition before the refinement, in other words, the condition in which the silk thread and the synthetic fiber do not shrink.

[0042]

And, the suture yarn for surgery considerably has a characteristics such as high strength as compared to the conventional suture yarn made of silk, especially, the decreasing rate of strength at the time of wetting process is considerably less as compared to the threads made of silk, making it very suitable for used in surgery. Moreover, the suture yarn for surgery has flexibility similar to that of the suture yarn made of silk, as well as excellent knot stability and operability. Moreover, it has less tissue reaction inside the body as it contains synthetic fibers. In addition, the advantage of this method is that the uniformity of the quality of the suture yarn manufactured by this method is higher than that of the combined thread that is formed by both the center thread and braiding yarn; in which the center thread is made of synthetic resin, and the braided thread is made of silk fiber.

BRIEF DESCRIPTION OF DRAWINGS

[Figure 1] It is an enlarged view showing the braided process in Application Example 1 of the present invention.

[Figure 2] It is an enlarged view showing the composite conjugated yarn, which is the composite yarn used in said Application Example.

[Figure 3] It is an enlarged view showing the composite interlaced yarn, which is the composite yarn used in Application Example 3 of the present invention.

[Figure 4] It is process chart showing the manufacturing method of the suture yarn in the above-mentioned Application Example.

[Figure 5] (a) is a schematic diagram showing the device to execute the testing method of the knot security test for the suture yarn for surgery of the present invention.

(b) is an explanatory drawing showing the square knot that is formed in the above-mentioned test.

[Figure 6] It is a schematic diagram showing the device to execute the testing method of the tie down test for the suture yarn for surgery of the present invention.

Explanation of Numerals

1 Silk thread
2 Synthetic fiber
3 Composite yarn
4 Center thread
5 Braiding yarn

Figure 1

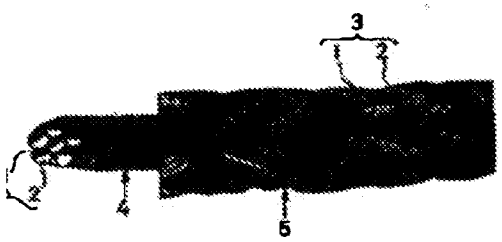


Figure 2

Figure 3

Figure 4

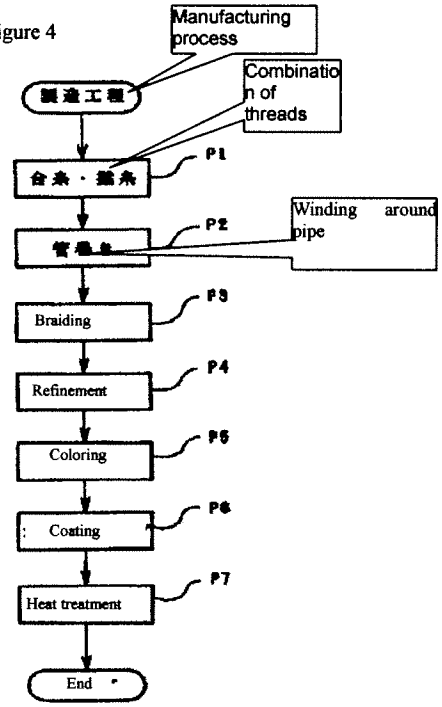
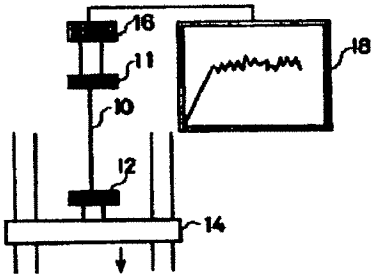


Figure 5

(a)



(b)

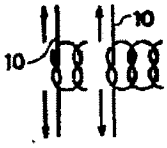
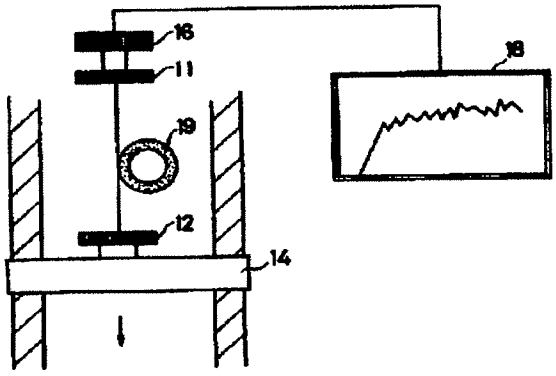


Figure 6



[Procedure corrections]
[Presented on] May 13, 1994
[Procedure correction 1]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0013
[Correction method] Change
[Correction contents]
[0013]
Operation of the invention

In the above mentioned method, at the time of braiding the two fibers, the silk fiber and synthetic fiber are not shrunk because refinement is not carried out until that time. Therefore, these two fibers can be braided excellently. After that, refinement is carried out. This process of carrying out refinement and hot stretching is more convenient than the process in which refinement is carried out before braiding as in the refinement process, and the synthetic fiber in the composite fiber shrinks more than the silk fiber. In said process, as braiding is carried out beforehand, this composite fiber is bound to each other. As a result, each braid of the string is strengthened and the surface of the thread also becomes smooth.

[Procedure correction 2]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0013
[Correction method] Change
[Correction contents]
[0014]

As compared to the silk suture yarn of the past, the suture yarn for surgery manufactured by this method has high tensile strength. Particularly, the decreasing rate in the strength in humid environment is remarkably less as compared to the silk suture yarn. However, the same ductility and excellent operability similar to that of the silk suture yarn is maintained. Moreover, it has less tissue reaction inside the body as it contains the synthetic fiber. In addition, it is preferred that the center thread and braided yarn both are formed from the composite yarn, the center thread is made of synthetic resin, and the braided thread is made of silk fiber. Uniformity of the material quality is higher than that of the composite yarn. And as for the rupture elongation, there is not much difference between silk fiber and braided yarn.

[Procedure correction 3]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0017
[Correction method] Change
[Correction contents]

[0017]

(1) Doubling and twisted thread (process P1 in Figure 4): The above mentioned composite yarn 3 forms the 6 ply yarn doubling, and it is twisted at 478T/M with a synthetic fiber machine to form the center thread 4 as shown in figure 1.

(2) Winding pipe (process P2): Braiding yarn 5 is winded (automatic pipe winder) automatically, it is winded around the pipe of braiding machine (braider), and at the same time, the center thread 4 is winded around the bobbin for the center thread.

(3) Braiding (process P3): While putting above-mentioned center thread 4 in the Braider, the composite yarn 3 is knitted in a 16-ply braided shape and braiding yarn 5 is formed surroundings said Center thread 4. At this time, each composite yarn 3 does not shrink as the refining process has not yet been carried out. Therefore, it can be easily braided without any disadvantages.

(4) Refinement (process P4): The entire suture yarn that consists of the above-mentioned center thread 4 and braiding yarn 5 is soaked in a Marseille soap solution, heated [at the temperature of] 85~90°C, and it is refined after around 1 hour. After washing by hot water for 25~30 minutes, air drying process is carried out.

(5) Dyeing (process P5): This is an optional procedure. For instance, the Hematine dye process is carried out when dyeing with black color.

(6) Coating (process P6): In this Application Example, as an ordinary method, beeswax and silicon are coated in this Application Example.

(7) Hot stretching processing (Setting heat: Process P7): Heat stretching machine is used. The processing speed, time, heating temperature, and draw ratio are properly adjusted to carry out the process. Concretely, the suture yarn has passed the furnace at about 2 m with a roller drawing machine, and the process is carried out for about 7 seconds at a fixed heating temperature and draw ratio. The heating temperature and the draw ratio will be described later.

[Procedure correction 4]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0020
[Correction method] Change
[Correction contents]

[0020]

Next, the Application Example 3 is explained. In this Application Example, it is a composite interlaced yarn 3 that is entangled by air during the reeling process for the silk fiber 1 and synthetic fiber 2 as shown in Figure 3. The hybrid silk fiber SNC 14-10 (silk fiber of 14 deniers and nylons of 10 deniers) is used as the raw material. As shown in the Table 1, the

suture yarn (SNC2-0) of corresponding USP2-0 was obtained by using the 12 ply in the center thread, 36 ply in the braiding yarn, and by executing each process with the conditions similar to that of Application Examples 1 and 2.

[Procedure correction 4]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0023
[Correction method] Change
[Correction contents]
[0023]
[Table 2]

Hot stretching process of Nylon thread Hybrid silk suture yarn

Sample	Temperature (°C)	Stretching ratio (%)	Straight		Surgical knot	
			Strength (kg)	Elasticity (%)	Strength (kg)	Elasticity (%)
SN 2 - 0	160	120	3.371	13.5	2.273	11.2
	180	120	3.427	12.6	2.334	10.5
	200	120	3.564	18.3	2.375	12.4
SNC2-0 (Composite interlaced yarn)	180	120	3.697	13.6	2.556	9.97
	200	120	3.655	14.6	2.543	10.3
	220	120	3.669	14.2	2.563	10.4
	200	110	9.242	32.3	6.157	24.6
	220	110	9.200	29.9	6.016	23.6
	200	120	9.350	25.8	6.138	19.2
SN 2	220	120	9.388	22.9	5.984	17.6

*Processing speed : 20m/min Time: Approximately 7sec

[Correction procedure 6]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0028
[Correction method] Change
[Correction contents]
[0028]
[Table 7]

*Strength of surgical knots of hybrid silk suture yarn at the time of humid climate

(Unit: kg/mm^2)

Suture yarn Specifications	Silk	SN Hybrid silk (Composite conjugated yarn)	SN Hybrid silk (Composite conjugated yarn)	SNC Hybrid silk (Composite interlaced yarn)	Nylon Braiding	Polyethylene Braiding
3－0	23.0	30.3	——	——	31.5	43.0
2－0	21.4	26.9	27.4	23.1	26.7	38.1
1－0	18.2	23.1	25.5	——	27.0	31.8
2	15.3	18.5	21.7	——	25.5	26.7

[Procedure correction 7]

[Name of document to be corrected] Detailed statement

[Name of item to be corrected] 0029

[Correction method] Change

[Corrected contents] [0029]

[Table 8]

Knot security and tie down test of nylon thread hybrid silk suture yarn

Sample		Knot Security			Tie down		
		2 surgical knots sliding resistance (kg)	3 surgical knots	4 surgical knots	Maximum value (kg)	Maximum value (kg)	Average value (kg)
SN 2-0	Dry	0.49	0／5	5／5	0.46	1.02	0.74
	Wet	0.60	0／5	5／5	0.55	0.75	0.65
SNC 2-0 (Composite interlaced yarn)	Dry	0.48	4／5	5／5	0.66	1.16	0.91
	Wet	0.75	0／5	5／5	0.66	0.85	0.76
Silk 2-0	DRY	0.31	3／5	5／5	0.53	0.92	0.73
	Wet	0.69	0／5	5／5	0.57	0.71	0.64
SN 1-0	Dry	0.57	4／5	5／5	0.78	1.40	1.09
	Wet	0.81	0／5	5／5	0.64	0.86	0.75
Silk 2-0	Dry	0.75	4／5	5／5	0.79	1.71	1.25
	Wet	0.78	0／5	5／5	0.76	0.98	0.87

* Knot security test result shows the number of cut ply after testing 5 ply. (Example 1/5 is 1 cut ply after testing 5 ply)

[Procedure correction 8]

[Name of document to be corrected] Detailed statement

[Name of item to be corrected] 0030

[Correction method] Change

[Corrected contents] [0030]
[Table 9]

Knot security of Polyester thread Hybrid silk suture yarn

Sample		Knot Security			Tie down		
SE 2-0							
	Dry	0.26	1/5	5/5	0.65	1.03	0.64
	Wet	0.56	0/5	5/5	0.52	0.68	0.60
SE 1-0							
	Dry	0.31	3/5	5/5	0.53	0.92	0.73
	Wet	0.69	0/5	5/5	0.57	0.71	0.64
Silk 1-0							
	Dry	0.90	4/5	5/5	0.74	1.22	0.98
	Wet	0.68	0/5	5/5	0.67	0.84	0.76
		0.75	4/5	5/5	0.79	1.71	1.25
		0.78	0/5	5/5	0.76	0.98	0.87

*Knot security test result shows the number of cut ply after testing 5 ply. (Example 1/5 is 1 cut ply after testing 5 ply)

[Procedure correction 9]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0033
[Correction method] Change
[Correction contents]
[0033]

In the Table 4 and 5, an experimental result regarding the tensile strength under dry/wet environment for the hybrid silk suture yarn was shown. As shown in the Table 4, the hybrid silk suture yarn of the nylon system meets the standard of the suture yarn in both the diameter and strength. /Silk the hybrid silk suture yarn of the polyester, the strength sufficiently meets the standard although the diameter is smaller (that is narrow) than the standard. Therefore, it can be expected that the suture yarn with high strength can be manufactured by increasing the raw material and increasing the diameter.

[Procedure correction 10]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] 0034
[Correction method] Change
[Correction contents]

[0034]

As for the above-mentioned hybrid silk suture yarn and conventional silk suture yarn, an experimental result about comparison of strength difference at the time of Wet and Dry process was shown in Table 6. As shown in this table, the strength of the silk suture yarn at the time of wetting process is compared with the strength at the time of drying process: it is decreased by around 20-30%, and the decrease rate is limited to about 10-20% in the hybrid silk suture yarn. Moreover, though the comparative experimental result of the tensile strength (= strength/cross sectional area) at the time of wetting process was shown in the Table 7, as seen in this table, the surgical knot's strength at the time of wetting process of the hybrid silk suture yarn is improved by more than 20-40% as compared with the ordinary silk suture yarn. In general, since the suture yarn for surgery is usually used in the presence of body fluid and blood, etc., the surgical knot's strength at the time of wetting process as stated above can be an extremely preferable matter for the suture yarn.

[Procedure correction 11]
[Name of document to be corrected] Detailed statement
[Name of item to be corrected] Brief description of the drawings
[Correction method] Change
[Correction contents]
[Figure 1] It is an enlarged view showing the suture yarn for surgery in Application Example 1 of this invention.

Translated by:

PHOENIX TRANSLATIONS

April 5, 2010